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PATENT

Attorney Docket No.: A-67616-2/RMS/DCF/KJC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

STUELPNAGEL et al.

Serial No. 09/636,387

Filed: August 9, 2000

For: ***Automated Information Processing in
Randomly Ordered Arrays***

) Examiner: B.J. Forman

) Group Art Unit: 1655

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CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on July 16, 2002

Signed: *Victoria T. Linn*
VICTORIA T. LINN

RESPONSE TO OFFICE ACTION

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This is in response to the office action mailed on April 16, 2002 for the above identified U.S. Patent application. This response is submitted on or before July 16, 2002, making this a timely response. However the Commissioner is authorized to charge any additional fees which

may be required, including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 06-1300(Our order No. A-67616-2/RMS/DCF/KJC).

Please enter the following claim amendments and consider the remarks herein.

IN THE CLAIMS

Please amend the claims as follows:

49. (Amended) A method of determining the presence of a target analyte in a sample comprising:

a) acquiring a first data image of a random array composition comprising:

i) a substrate with a surface comprising discrete sites;

ii) a population of microspheres comprising at least a first and a second

subpopulation each comprising a bioactive agent, wherein at least one of said

subpopulations does not contain an optical signature; and

iii) a fiducial,

wherein said microspheres are randomly distributed on said surface such that said

discrete sites contain microspheres;

b) using said fiducial to register said first data image to create a registered first data image;

c) contacting said random array composition with said sample;

d) acquiring a second data image from said array with said sample;

e) registering said fiducial to register said second data image to create a registered second data image; and

C1
a) f) comparing said first and said second registered data images to determine the presence or absence of said target analyte.

50. The method according to claim 49 wherein said random array comprises a fiber optic bundle and the registration of said first data image utilizes a fiducial fiber.

51. The method according to claim 49 wherein said random array comprises microspheres and the registration of said first data image utilizes a fiducial microsphere.

52. The method according to claim 49 wherein the registration of said first data image utilizes a fiducial template.

53. The method according to claim 49 wherein said bioactive agents are proteins.

54. The method according to claim 49 wherein said bioactive agents are nucleic acids.

61. (Amended) A method of determining the presence of a target analyte in a sample comprising:

- C2
- a) providing a registered first data image of a random array composition comprising:
 - i) a substrate with a surface comprising discrete sites;

C₂
and

ii) a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent, wherein at least one of said subpopulations does not contain an optical signature; and

iii) a fiducial,

wherein said microspheres are randomly distributed on said surface such that said discrete sites contain microspheres;

- b) contacting said random array composition with said sample;
- c) acquiring a second data image from said array with said sample;
- d) using said fiducial to register said second data image to create a registered second data image; and
- e) comparing said first and said second registered data images to determine the presence or absence of said target analyte.

62. The method according to claim 49, wherein said substrate is selected from the group consisting of glass and plastic.

63. The method according to claim 49 or 62, wherein said registration of said first data images utilizes a fiducial edge.

64. The method according to claim 49 or 62, wherein at least a first edge of said array is a fiducial edge.

65. The method according to claim 51, 52, 53 or 54, wherein said substrate is selected from the group consisting of glass and plastic.

66. The method according to claim 49 or 62, wherein each subpopulation comprises a unique optical signature.

67. The method according to claim 66, wherein said unique optical signature is a bleed-through signature.

68. (Amended) The method according to claim 49 or 62, wherein each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand whereby the identification of the bioactive agent is elucidated.

69. The method according to claim 50, wherein said array comprises at least three fiducials, and each of said fiducials is a fiducial fiber.

70. The method according to claim 69, wherein at least one of said fiducial fibers has a different shape from the others.

71. The method according to claim 69, wherein at least one of said fiducial fibers has a different color from the others.

72. The method according to claim 51, wherein said registration utilizes at least three fiducials and each of said fiducials is a fiducial microsphere.

73. The method according to claim 72, wherein at least one of said fiducial microspheres has a different size from the others.

74. The method according to claim 72, wherein at least one of said fiducial microspheres has a different color from the others.

75. The method according to claim 72, wherein at least one of said fiducial microspheres does not comprise a label.

REMARKS

Claims 49-54 and 61-75 are currently pending. Claims 49 and 61 have been amended. Support for amendments of claims 49 and 61 is found in the specification at page 20, line 9. A “clean” claim set to be introduced in place of the original claims is provided above. A version showing changes made is attached hereto for the Examiner’s convenience. An appendix of the current pending claims is also attached for the Examiner’s convenience.

Rejections based under 35 U.S.C § 102

Claims 49-63, 65-69 and 71-74 are rejected under 35 U.S.C § 102(e) as being anticipated by Walt et al. (U.S. Patent No. 6, 327, 410 B1, filed September 11, 1998) in view of the definitions of Morris ed. (Academic Press Dictionary of Science and Technology, Academic Press, 1992, page 821).

Walt et al. is directed to a microsphere-based analytic chemistry system. Walt et al. teaches the use of microspheres distributed on the surface of a substrate wherein each microsphere contains an optical signature. Regarding amended claims 49 and 61, Walt et al. is silent with respect to teaching at least one subpopulation of microspheres not having an optical signature.

In regards to claims 49 and 61 (from which all other claims depend), the Examiner states that Walt et al. teaches all the elements of claims 49 or 61. The amended claims as provided herein teaches at least one of said subpopulations does not have an optical signature.

The law is well established that in order to anticipate a claim, the prior art must disclose “each and every element” of the claimed invention. SSIH Equipment S.A.v. U.S. Inc. Int’l. Trade

Commission, 218 USPQ 678, 688 (Fed. Cir. 1983). As stated by the Federal Circuit in In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." (Emphasis added). See also Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 33 USPQ2d 1496 (Fed. Cir. 1995).

Walt et al. does not disclose "each and every element" of the claimed invention. Namely, Walt et al. is silent with respect to teaching beads without optical signatures. In addition, Applicants traverse the rejection of the dependent claims. However, Applicants submit that the rejection of these claims is moot in light of the claim amendments submitted herein. Accordingly, the reference does not anticipate the present claims, and the rejection is improper.

Applicants respectfully request the withdrawal of the rejection.

Rejection based on 35 U.S.C § 103

Claims 64, 70 and 75 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Walt et al. (U.S. Patent No, 6,327,410, filed 11 September 1998) in view of Augenlicht (U.S. Patent No. 4,981,783, filed 16 April 1986) and in view of the definitions of Morris ed. (Academic Press Dictionary of Science and Technology, Academic Press, 1992, page 821).

The distinctions between Walt et al. and the claims of the present invention are discussed above and are incorporated herein.

Augenlicht et al. is directed to detecting the expression of cloned genes by immobilizing nucleic acid from individual clones arranged in a pattern on a substrate such as nitrocellulose and hybridizing nucleic acid probes to the immobilized nucleic acid with subsequent determination

of the level of expression of individual genes in a sample. Augenlicht et al. teaches the use of fiducial markings to locate the position of the individual clones. Augenlicht et al. does not teach the use of fiducials in an array comprising microspheres distributed on a substrate.

Claims 64, 70 and 75 are all dependent from claim 49 and are drawn to a method of determining the presence of a target analyte in a sample through the use of subpopulations of microspheres randomly distributed on a surface, wherein at least one subpopulation does not contain an optical signature and the use of fiducials to register images of the random array, wherein a first edge of said array is a fiducial edge (claim 64); wherein at least one of said fiducial fibers has a different shape from the others (claim 70); and wherein at least one of said fiducial microspheres does not comprise a label (claim 75).

To establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In addition, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the claim limitations must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner states that it would have been obvious to one of ordinary skill in the art to modify the substrate of Walt et al. or to modify the fiducial-containing array of Walt et al. to encompass a fiducial of different shape for the expected benefit of rapid and accurate target analysis as suggested by Augenlicht (claims 64 and 70)(column 8, 15-29), or to modify the different sized fiducials of Walt et al. providing unlabeled fiducials of different size (claim 75)

for the obvious benefit of convenience and economy of time and labor. Applicants respectfully traverse.

There is lacking any suggestion or motivation to modify the references or combine reference teachings. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F 2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). There is no suggestion in either reference of modifying or combining to reach the claims of the present invention.

The Examiner's attention is respectfully drawn to In re Lee, 61 USPQ2d 1430 (CA FC 2002). In this case, the Examiner rejected the claims under 35 U.S.C. §103 and stated that the required motivation "would be that the automatic demonstration mode is user friendly and it functions as a tutorial". *Id* at 1435. The Federal Circuit stated that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is "basic knowledge" or "common sense". The Board's finding must extend to all material facts and must be documented on the record, lest the "haze of so-called expertise" acquire insulation from accountability. "Common knowledge" and "common sense", even if assumed to derived from the agency's expertise, do not substitute for authority when the law requires authority." (citing In re Zurko, 59 USPQ2d 1693 (CA FC 2001); see Lee, 1434-1435).

In this case, the Examiner has essentially used impermissible hindsight and "common sense" to conclude that the combination of these two references leads to "expected benefit of rapid and accurate target analysis or obvious benefit of convenience and economy of time and labor". This is legally incorrect under the Federal Circuit's analysis because the Examiner has

cited no authority for these assertions. Accordingly, Applicants submit that one of ordinary skill in the art would not have been motivated to combine the references.

However, even assuming *arguendo*, that there was motivation, Applicants note that the cited references do not teach all of the claim limitations. The present invention not only teaches the use of fiducial markings in conjunction with microspheres distributed on a surface, but also teaches at least one subpopulation of microspheres distributed on a surface does not have an optical signature. Neither Walt et al. nor Augenlicht et al. teach or suggest this aspect of the present invention.

Since neither Walt et al. or Augenlicht et al. teach or suggest the use of at least one subpopulation of microspheres without optical signatures, which is an element of both claims 64, 70 and 75, the requirement that the prior art reference (or references when combined) must teach or suggest all the claim limitations has not been met. Therefore a *prima facie* case of obvious has not been satisfied.

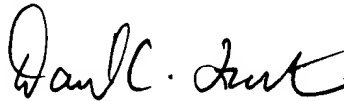
Accordingly, Applicants respectfully request the withdrawal of the rejection.

CONCLUSION

Applicants submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

Respectfully submitted,

DORSEY & WHITNEY LLP



Dated: 7/16/02

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